K081776

JUL 22 2008

510(k) Summary

This summary information is being submitted in accordance with the requirments of 21 CFR 807.92(c)

Owner:

Name:	Omega Critical Care
Address:	2 Cairn Court West Nerston East Kilbride G74 4NB Unitied Kingdom
Telephone:	+44 1355 265733
Facsimile:	+44 1355 239094
Contact:	Alan Short, Director of Quality & Regulatory Affairs Omega Critical Care
Date of Summary:	19th June 2008

Device Information:

Trade Name:	Continuous Cardiac Output Pulmonary Artery Catheter and Continuous Cardiac Output Monitor
Common Name:	Pulmonary Artery Catheter and Cardiac Output Monitor
Classification Name:	Flow-directed catheter and single function, pre-programmed diagnostic computer per 21 CFR 870.1240 and 870.1435 respectively
Predicate Device:	The modified device is substanttially equivalent to the previously cleared Continuous Output Pulmonary Artery Catheter and Continuous Outout Monitor, 510(k) number K993245

Device Description:	The Continuous Cardiac Ouptut Pulmonary Artery Catheter, (truCATH), is a six lumen heparin coated, polyvinyl chloride (PVC) flow directed Pulmonary Artery Catheter. Once placed the proximal extensions of the catheter are attached to the second part of the system, the monitor. The Continous Cardiac Output Monitor, (truCCOM), is a microprocessor based computer which when interfaced with the truCATH, continuously calculates and displays cardiac output. The monitor calculates cardiac output based upon a thermodynamic principle of heat transfer using thermal power produced by the termal coil area on the Catheter. Alternatively the monitor can also be used by the clinician to measure cardiac output intermittently through using the injectate capabilities of the catheter.
Intended Use:	The continuous cardiac output Pulmonary Artery Catheter and Continuous Cardiac Outoput monitor systems intended use is for the assessment of the patients haemodynamic condition though direct intra-cardiac (right heart) and pulmonary artery pressure monitoring, cardiac outut determination and for infusing solutions. The distal port on the catheter also allows for the sampling of veous blood.

Comparison to Predicate Device:	The modifications in comparison to the previously cleared device are as follows (these modification do not affect the intended use of the device or alter the fundemental scientific technology of the device) <u>Monitor</u> - User Interface Improvements - Re-formatting of history files - Enable analogue output - Implementation of an updated equation for the calculation of cardiac output - Optomisation of system response - Modification of audible alarms to default enabled - Correction of minor bugs
Summary of non-clinical tests:	The following outlines the testing performed, as a result of the risk analysis, to demonstrate substantial equivelance to the predicate device <u>Monitor</u> - Software Verification & Validation - In-vitro testing in Right Hand Circulatory System - In-vivo testing in Swine Models
Conclusion:	The above test results confirmed the modified device met or exceeded the same specifications as that of the predicate device and is therefore substantially equivalent with respect to safety and efficacy to the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2008

Omega Critical Care Limited
c/o Mr. Lucio E. Jannetta
Omega House
2 Cairn Court
Nerston West
East Kilbride
Scotland G74 4NB

Re: K081776
Trade/Device Name: Continuous Cardiac Pulmonary Artery Catheter (truCATH & truCATH.*ip*) & Continuous Cardiac Output Monitor (truCCOM)
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-function, preprogrammed diagnostic computer
Regulatory Class: Class II
Product Code: DXG
Dated: June 5, 2008
Received: June 23, 2008

Dear Mr. Janetta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~K993245~~ K081776

Device Name: Continuous Cardiac Output Pulmonary Artery Catheter (truCATH & truCATH.*ip*) & Continuous Cardiac Output Monitor (truCCOM)

Indications for Use: The Continuous Cardiac Output Pulmonary Artery Catheter and Continuous Cardiac Output Monitor systems intended use is for the assessment of a patients haemodynamic condition through direct intracardiac (right heart) and pulmonary artery pressure monitoring, cardiac output determination and for infusing solutions. The distal port on the catheter also allows for sampling of venous blood.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) ~~AND/OR~~ Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081776